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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,320	02/13/2001	Bernhard H. van Lengerich	BVL-102A	9819

7590 03/18/2004

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EXAMINER

WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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2/13/04

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS**OFFICE ACTION SUMMARY**☒ Responsive to communication(s) filed on 11/14/03☐ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).**Disposition of Claims**☒ Claim(s) 25-35, 37-43, 46, 47, 50, 52-62, 64-71, 73, 75-76, 79, 81-104 is/are pending in the application.Of the above, claim(s) 26, 32, 33, 41, 43, 47, 50, 53, 60, 68, 71, 86-89, 94 is/are withdrawn from consideration.☒ Claim(s) 25, 27-31, 34-35, 37-40, 42, 46, 90-93, 101 is/are allowed.☒ Claim(s) 52, 54-59, 61, 62, 64-67, 69, 70, 73, 75-76, 79, 81-85, 95-97 is/are rejected.☒ Claim(s) 102-105 is/are objected to.☐ Claim(s) _____ are subject to restriction or election requirement.**Application Papers**☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on _____ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been☐ received.☐ received in Application No. (Series Code/Serial Number) _____☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☒ Notice of Reference Cited, PTO-892☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 8/12/03, 11/13/03☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152T.D.
APPROVED

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Re applicants inquiry regarding nonelected claims in the remarks filed 6/18/03, claims 26, 41, 50, 53, 68, 86-89, 98-99, 106-107 are directed to non-elected matrices. Claims 42, 47, 71, 90 and 100 are directed to nonelected active agents. Claims 32, 33, and 60 are directed to nonelected release-rate controlling components. Claim 94 is directed to a nonelected encapsulant form.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 52, 54-59, 61, 62, 64-67, 69, 70, 73, 75-76, 79, 81-89, 90-93, 95-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vagesna et al in view of Cavalier Vesely et al, Hampton et al and Craig et al.

Vagesna et al teach non-baked granules comprising cholestyramine, oil, and a grain or flour (abstract). 10-15% oil is disclosed (column 2 lines 65-66). 15-17% water is specified (column 6 lines 9-11). Starch is disclosed (column 2 line 47). control of high cholesterol levels is specified (column 1 lines 10-13). A substantially homogenous mixture is disclosed (column 6 lines 15-18). Wheat is specified (column 3 lines 28-31). Tablets are disclosed (abstract).

Cavaliere Vesely teaches lactobacilli for the treatment of hypercholesterolemia (abstract). Pellets and tablets are specified (column 3 lines 19-22). 10-95% is disclosed (column 2 lines 30-34).

It would have been obvious to one of ordinary skill to add lactobacilli to the composition of Vegesna et al to achieve the additional beneficial effect of a second agent for treating high cholesterol in view of Cavaliere Vesely et al. As to the claimed durum wheat, gluten is a well-known binder for tablets (Hampton et al column 1 lines 57-58). And durum wheat is well known as high in gluten content (Craig et al column 1 lines 31-34). Thus, it would be an obvious expedient to choose durum for the Vegesna et al wheat to achieve the beneficial effect of the tablet binding property of Gluten contained therein. As to the claimed controlled release, such a limitation is merely an intended use.

As to the particular claimed pellet size, shape, and density it is within the skill in the art to select optimal parameters such as ratios or weight percents of components in order to achieve a particular beneficial effect. In re Boesch 205 USPQ 215 (CCPA 1980). Therefore, the size, shape and density instantly claimed are not considered critical absent evidence showing unexpected and superior results.

As to the claimed coating, such is well known in the particle art for purposes such as waterproofing or delayed release.

Claim 95 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants elected a probiotic as encapsulant yet claim a liquid form of encapsulant. No where in the specification is it disclosed how to make the probiotic in liquid form.

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Claims 25, 27-31, 34-35, 37-40, 42, 46, 90-93, 101 are allowed.

Claims 52, 54-59, 61, 62, 64-67, 69, 70, 73, 75-76, 79, 81-85, 90-93, 95-97 are rejected.


Claims 102-105 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication should be directed to Edward J. Webman at telephone number 571-272-0633.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Webman/tgd

February 18, 2004


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